



BRIGHAM AND
WOMEN'S HOSPITAL

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Boston, Massachusetts 02115

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Mark B. McClellan, MD, PhD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
5600 Fishers Land
Rockville, MD 20857

Dear Commissioner McClellan:

As a practicing gynecologist and member of *Physicians for Reproductive Choice and Health®* (PRCH), I strongly support the overwhelming evidence-based and public health imperative for over-the-counter access to emergency contraceptive pills (ECPs).

Contraception, regrettably, is neither universal nor fail-proof. Unintended pregnancies occur in both the small percentage of women who don't use contraception, and in women for whom contraception fails. Of all the women who experienced an unintended pregnancy, more than half - 53 percent - were using contraception at the time of conception.

Extensive research also demonstrates that ECPs are extremely safe, including when self-administered. The hormones in ECPs have been used for more than thirty years as daily birth control by tens of millions of women, and serious complications have been extremely low.

Medical decisions should be rooted firmly in scientific evidence. Research on emergency contraception - including numerous randomized trials, data on actual use, and label-comprehension studies - has revealed that prescription-only status of ECPs is both gratuitous and harmful. Prolific research on ECPs documents their safety, efficacy, and ease-of-use, along with the economic benefits of OTC status for individuals, institutions, and public systems.

Professional and public support of the OTC switch is obvious, as more than 70 organizations are signators to the 2001 Citizen's Petition for Status Change for Emergency Contraception. Among the numerous medical and public health organizations supporting the switch are: the AMA, ACOG, the Association of Reproductive Health Professionals, Planned Parenthood Federation of America, and Physicians for Reproductive Choice and Health®.

Condoms and spermicides are widely available over-the-counter. As a product that could drastically reduce the rate of unintended pregnancy, ECPs should share their over-the-counter status. Simply stated, emergency contraception is effective and safe and deserves to be available over-the-counter. I highly support over the counter status, and hope the FDA will follow science and make this a reality.

Sincerely,

Alisa B. Goldberg, MD, MPH
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Harvard Medical School & Brigham and Women's Hospital and
Associate Medical Director,
Planned Parenthood League of Massachusetts



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